COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 28-II-2006
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NOT FOR PUBLICATION

COMMISSION DECISION

of 28-II-2006

amending the marketing authorisation for "Lysodren - Mitotane", a medicinal product for human use, granted by Decision C(2004)1765

(Text with EEA relevance)

(ONLY THE FRENCH TEXT IS AUTHENTIC)

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amending the marketing authorisation for "Lysodren - Mitotane", a medicinal product for human use, granted by Decision C(2004)1765

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93[3], and in particular the third subparagraph of Article 4(5) thereof,

Having regard to the notifications submitted by Laboratoire HRA Pharma under Article 4(1) of Regulation (EC) No 1085/2003,

Whereas:

(1) The European Medicines Agency acknowledged, between 1 August 2005 and 1 February 2006, the validity of the notification(s) for minor variations of type IA, informing the marketing authorisation holder accordingly, and has prepared a list of the notification(s). The variation(s) took effect from the date of the communication from the European Medicines Agency concerning the validation.

[1] OJ L 214, 24.8.1993, p. 1. Regulation as last amended by Regulation (EC) No 1647/2003 (OJ L 245, 29.9.2003, p. 19).
[2] OJ L 136, 30.4.2004, p. 1
[3] OJ L 159, 27.6.2003, p. 24.

(2) The marketing authorisation should be updated, and Decision C(2004)1765 of 28 April 2004 amended accordingly.

(3) For the sake of clarity and transparency, it is advisable, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C (2004)1765 should therefore be replaced,

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2004)1765 is amended as follows:

1) The following list of notifications for minor variations is added to the updated marketing authorisation.

Application number	Scope (EU numbers affected)
EMEA/H/C/521/IA/0002	1 (IA) (EU/1/04/273/001)
EMEA/H/C/521/IA/0003	6.a (IA) (EU/1/04/273/001)

2) Annex III is replaced by the text set out in the Annex III to this Decision.

Article 2

This Decision is addressed to Laboratoire HRA Pharma, 19 rue Frédérick Lemaître 75020 Paris, France.

Done at Brussels, 28-II-2006

For the Commission
Günter VERHEUGEN
Vice-President of the Commission